K023879

FEB 05 2003

3.0 Summary of Safety and Effectiveness Information - 510(k) Summary

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Lisa M. Boyle
DEVICE NAME:	Small Titanium Wrist Fusion Plate
CLASSIFICATION:	Class II, § 888.3030 – Single / multiple component metallic bone fixation appliance and accessories
PREDICATE DEVICE:	• Synthes Straight Wrist Fusion Plate • Biomet® Colles Fracture Plate
DEVICE DESCRIPTION:	The Synthes small titanium wrist fusion plate is a low profile plate with a 2.1 mm thickness, a proximal width of 8mm and a distal width of 6 mm. The plate uses a total of 8 holes across the 107 mm pre-contoured length. There are proximal and distal holes which utilizes 2.7 mm and 2.4mm screws. Limited contact undercuts are included to minimize plate to bone contact and the ends are tapered in thickness for minimal soft tissue irritation.
INTENDED USE:	The Synthes (USA) Small Titanium Wrist Fusion Plate is intended for use in plate fixation for wrist arthrodesis in patients with disorders such as cerebral palsy, brachial plexopathy, spinal cord injuries, and trauma. This plate addresses the smaller stature and pediatric patient by having a low profile construct and utilizing small screws.
MATERIAL:	CP Titanium

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2003

Ms. Lisa M. Boyle
Regulatory Associate
Synthes (USA)
P. O. Box 1766
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K023879
Trade/Device Name: Synthes Small Titanium Wrist Fusion Plate
Regulation Numbers: 21 CFR 888.3030
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: November 18, 2002
Received: November 21, 2002

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

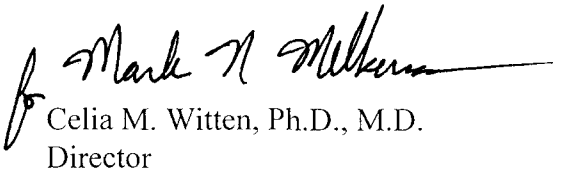
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K023879

Device Name: Synthes (USA) Small Titanium Wrist Fusion Plate

Indications/Contraindications:

The Synthes (USA) Small Titanium Wrist Fusion Plate is intended for use in plate fixation for wrist arthrodesis in patients with disorders such as cerebral palsy, brachial plexopathy, spinal cord injuries, and trauma. This plate addresses the smaller stature and pediatric patient by having a low profile construct and utilizing small screws.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_
(Per 21 CFR 801.109)

for Mark N Milhran
(Division Sign-Off)

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